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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/731,973	12/09/2003	Eric R. First	17637 (BOT)	6433

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EXAMINER	
TONGUE, LAKIA J	

ART UNIT	PAPER NUMBER
1645	

MAIL DATE	DELIVERY MODE
06/25/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/731,973	FIRST, ERIC R.	
	Examiner	Art Unit	
	LAKIA J. TONGUE	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 May 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,8-10 and 12-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,8-10 and 12-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 12, 2008 has been entered.

Applicant's response filed on May 12, 2008 is acknowledged. Claims 1-6, 8-10 and 12-27 are pending. Claims 1, 12 and 25 have been amended. Claims 1-6, 8-10, and 12-27 are currently under examination.

Objections Withdrawn

1. In view of Applicant's amendment, the objection to claims 22 and 24 for depending on rejected based claims is withdrawn.

Rejections Withdrawn

2. In view of Applicant's argument the rejection of claims 12-16 and 19-23 under 35 U.S.C. 102(b) as being anticipated by Orloff et al. (Surg 1999; 121(4): 410-413) is withdrawn.

Rejections Maintained

Claim Rejections - 35 USC § 102

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. The rejection of claims 1-6, 8-10, 12-21 and 25-27 under 35 U.S.C. 102(e) as being anticipated by Kwon (U.S. 2004/0087893 A1), as evidenced by Allergan (pages 1-4, http://www.allergan.com/download/BotoxPI.pdf, accessed on March 22, 2007) is maintained for the reasons set forth in the previous office action.

Applicant argues that:

1) The claims require that the botulinum toxin administration is per session.

2) Kwon states that the SSP system may be used to deliver botox to more efficiently and safely remove or reduce wrinkle formation and skin aging. However, Kwon makes no distinction as to whether botox is to be administered in non-paralytic or paralytic amounts.

3) It cannot be argued that Kwon discloses the presently claimed invention since Kwon is directed to administration using solid dissolvable perforators that optionally incorporate a drug such that the drug is released into the body upon dissolution of the solid perforators.

4) Kwon specifically teaches away from the conventional hollow needle administration required by claims 1 and by 12 by stating that in "contrast to conventional hollow needle technologies, the SSP system includes a solid matrix of dissolvable or

biodegradable material that optionally holds one or more selected drugs and is formed into one or more perforators".

Applicant's arguments have been considered, but have not been deemed persuasive.

The claims are drawn to a method for treating a skin disorder in a patient in need thereof, the method comprising the step of administering a therapeutically effective amount of a liquid solution comprising a botulinum toxin to a location of a skin disorder of the patient, wherein the administration of the botulinum toxin reduces at least one symptom of the skin disorder, thereby treating the skin disorder; wherein the solution is administered by intradermal injection or subdermal injection per session; wherein the skin disorder comprises a wart, callus, a swelling or scarring of a nerve that connects two toes, or a bunion; and wherein the botulinum toxin administered is less than the amount used to paralyze a muscle.

With regard to Point 1, absent evidence to the contrary, Kwon necessarily administers a therapeutically effective amount of a liquid solution of botulinum toxin by intradermal injection or subdermal injection per session.

With regard to Point 2, while Kwon may not explicitly disclose that botox is to be administered in non-paralytic or paralytic amounts, the methods of the instant invention and Kwon are identical. Claim 1 is drawn to a method for treating a skin disorder in a patient in need thereof, the method comprising the step of administering a therapeutically effective amount of a liquid solution comprising a botulinum toxin to a location of a skin disorder of the patient, wherein the administration of the botulinum

toxin reduces at least one symptom of the skin disorder, thereby treating the skin disorder; wherein the solution is administered by intradermal injection or subdermal injection per session; wherein the skin disorder comprises a wart, callus, a swelling or scarring of a nerve that connects two toes, or a bunion; and wherein the botulinum toxin administered is less than the amount used to paralyze a given muscle. The claims as well as the specification are silent with regard to what amount is a sufficient amount to paralyze a muscle. Consequently, absent evidence to the contrary, Kwon necessarily administers an amount of botulinum toxin which is less than the amount used to paralyze a muscle.

With regard to Point 3, the method is drawn to a method that comprises the step of administering botulinum toxin to a patient to treat a wart, callus, a swelling or scarring of a nerve that connects two toes, or a bunion. Kwon discloses a method of treating corns, warts, calluses, bunions and keratoses comprising administering a therapeutically effective amount of botulinum toxin. While the Kwon reference discloses the use of a SSP (which uses needles, blades or other perforators), at the point of administration the botulinum toxin is in a solution form, which is indicative of a liquid solution. Although Kwon uses a SSP, perforators by definition (i.e. to pierce or penetrate) meet the limitation of the instant claims.

With regard to Point 4, in response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the use of conventional hollow needle technologies) are not recited in the rejected claim(s). The claims are limited to intradermal or subdermal

injection only. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

As previously presented, Kwon discloses a method of administering a safe and effective amount of botulinum toxin for treating lesions or abnormal skin features, such as pimples, corns, warts, calluses, bunions and keratoses (see page 6, paragraph 0077). Moreover, Kwon discloses administering the botulinum toxin via a patch (topical). Kwon discloses that a design of an SSP patch includes an array of perforators that is porous and optionally serves as a drug reservoir and the active ingredients are contained in the perforator. Kwon discloses that the design is ideal for potent drug delivery, for administering small doses systemically, or for topical applications (see page 5, paragraph 0049).

The instant specification has characterized a therapeutically effective amount as an amount to alleviate a symptom of a skin disorder (see page 21), inherently Kwon has administered a therapeutically amount of botulinum toxin. With regard to claims 8-10, due to the mode of action of botulinum toxin its administration would necessarily reduce a pain and/or inflammation associated with the skin disorder as well as reduce the size of a disorder selected from the group consisting of warts, corns, calluses, a swelling or scarring of a nerve that connects two toes, hammertoes and bunions. Moreover, in view of all disclosed above the method necessarily encompasses intradermal or subdermal injection as well as a topical wherein the composition is a cream or lotion.

New Grounds of Rejection

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-6, 8-10 and 12-27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a method for treating a skin disorder in a patient in need thereof, the method comprising the step of administering a therapeutically effective amount of a liquid solution comprising a botulinum toxin to a location of a skin disorder of the patient, wherein the administration of the botulinum toxin reduces at least one symptom of the skin disorder, thereby treating the skin disorder; wherein the solution is administered by intradermal injection or subdermal injection per session; wherein the skin disorder comprises a wart, callus, a swelling or scarring of a nerve that connects two toes, or a bunion; and wherein the botulinum toxin administered is less than the amount used to paralyze a muscle.

The claims are drawn to a method for treating a skin disorder in a patient wherein the botulinum toxin administered is less than the amount used to paralyze a muscle. The specification discloses that the amount of Clostridial toxin to be administered can vary according to the particular characteristics of the skin disorder being treated (see

page 29, lines 12-15). However, the specification is silent with regard to how to determine what an effective amount equates to that is less than the amount used to paralyze a given muscle. The specification is equally silent with regard to which muscle and what size muscle equates to less than the amount used to paralyze and yet remain sufficient to effectively treat a skin disorder and not have detrimental affects on the patient. To fulfill the written description requirements set forth under 35 USC § 112, first paragraph, the specification must describe at least a substantial number of the members of the claimed genus or alternatively describe a representative member of the claimed genus, which shares a particularly defining feature common to at least a substantial number of the members of the claimed genus, which would enable the skilled artisan to immediately recognize and distinguish its members from others, so as to reasonably convey to the skilled artisan that Applicant has possession of the claimed invention.

The specification does not disclose distinguishing and identifying features of a representative number of members of the genus to which the claims are drawn.

A representative number of species means that the species that are adequately described are representative of the entire genus. The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, disclosure of drawings, or by disclosure of relevant identifying characteristics, for example, structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such

identifying characteristics, sufficient to show the Applicant was in possession of the claimed genus.

See Vas-Cath, Inc. v. Mahurkar, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Federal Circuit, 1991). Furthermore, the written description provision of 35 USC § 112 is severable from its enablement provision; and adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016.
The Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, paragraph 1, ``Written Description" Requirement (66 FR 1099-1111, January 5, 2001) state, "[p]ossession may be shown in a variety of ways including description of an actual reduction to practice, or by showing the invention was 'ready for patenting' such as by disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the Applicant was in possession of the claimed invention" (Id. at 1104). Moreover, because the claims encompass a genus of variant species, an adequate written description of the claimed invention must include sufficient description of at least a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics sufficient to show that Applicant was in possession of the claimed genus. However, factual evidence of an actual reduction to practice has not been disclosed by Applicant in the specification; nor has Applicant shown the invention was "ready for patenting" by disclosure of drawings or

structural chemical formulas that show that the invention was complete; nor has Applicant described distinguishing identifying characteristics sufficient to show that Applicant were in possession of the claimed invention at the time the application was filed. Therefore, for all these reasons the specification lacks adequate written description, and one of skill in the art cannot reasonably conclude that the Applicant had possession of the claimed invention at the time the instant application was filed.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-6, 8-10 and 12-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 12 and 25 are rendered vague and indefinite by the use of the phrase "wherein the botulinum toxin administered is less than the amount used to paralyze a muscle". It is unclear what is meant by said phrase, as it is not explicitly defined in the specification. What amount is "less than the amount used to paralyze a muscle"? What muscle is this amount based off of? As written, it is impossible to determine the metes and bounds of the claimed invention.

Conclusion

6. No claim is allowed.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAKIA J. TONGUE whose telephone number is (571)272-2921. The examiner can normally be reached on Monday-Friday 8-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley can be reached on 571-272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

LJT
6/17/08

/Robert A. Zeman/
for Lakia J. Tongue, Examiner of Art Unit 1645
June 23, 2008